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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,652	09/10/1999	PRAMOD K. SRIVASTAVA	8449-025-999	3088

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,652

Applicant(s)

Srivastava et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/09/02 and 1/02/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-19, 21, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-19, 21, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, drawings, and remarks, filed 9/09/02, and election of species, filed 1/02/03 are acknowledged. The drawings have been found to be acceptable by the Examiner.

2. Upon reconsideration, particularly in view of Applicant's citing of MPEP 806.03, all species requirements have been withdrawn and all claims have been rejoined.

Claims 1-2 and 6-19, 21 and 32 are under examination.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16-18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record as set forth in Paper No. 13, mailed 3/07/02.

Applicant arguments, filed 9/09/02, have been fully considered but are not found persuasive. Applicant argues that "Claim 1 recites "administration of a composition" while claims 16-18, which depend on claim 1, recite the range for the amount of hsp [heat shock protein]-peptide complex present in the composition of claim 1 that is administered. Consequently, the amount of hsp-peptide complex administered, i.e. the dose, is the amount of hsp-peptide complex present in the composition. The amount need not be recited in terms of a concentration rather than weight."

It is the Examiner's position that the claims remain indefinite as they do not disclose a specific amount, or range of amounts, of hsp composition to be administered to a mammal. Applicant's argument that, "the amount of hsp-peptide complex administered, i.e. the dose, is the amount of hsp-peptide complex present in the composition," fails to take into account both the amount of hsp in relation to peptide (concentration), and the amount of composition administered to the mammal (dosage). While the composition might contain a specific amount of hsp, e.g., 100 μ g, said 100 μ g of hsp might be present in a gram of composition or a ton of composition. Further, the claims fail to recite how much of the composition is to be administered.

Accordingly, the actual dosage of the composition to be administered to the mammal remains indefinite.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2, 6-19, 21, and 32 are rejected under 35 U.S.C. 103(a) each as being unpatentable over WO 95/15338 (1995, IDS, of record) and U.S. Patent No. 5,993,803 (1999, of record), in view of U.S. Patent No. 5,750,119 (1998, of record) and Cohen (1992, of record), for the reasons of record as set forth in Paper No. 13, mailed 3/07/02.

Applicant arguments, filed 9/09/02, have been fully considered but are not found persuasive. It is noted that Applicant does not dispute that the prior art teaches that both hsp60 and cpn10 can be used in a method of treating or preventing rejection of a graft. Applicant does, however, argue the conclusion that one of ordinary skill in the art at the time the invention was made would find that hsps were essentially interchangeable. Specifically, Applicant argues that in view of the Cohen et al. reference and '119 patent, one of ordinary skill in the art at the time the invention was made would not have found hsps to be interchangeable. In this regard Applicant does not argue that the Cohen et al. reference teaches that heat shock proteins are highly conserved and related, "Members of each hsp subfamily are produced by widely different creatures. Nevertheless, they are characterized by high degrees of sequence homology." Applicant's argument is then that, while hsp members within subfamilies are similar, "a BLAST search has revealed that there is little to no significant sequence homology between members of different hsp subfamilies."

Presumably then Applicant is arguing that the different hsps of the claims, gp96, hsp70, and hsp90, cannot be considered to be similar enough, by sequence homology alone, to be expected to have similar properties. It is the Examiner's position that Applicant's instant argument is inconsistent with Applicant's previously presented positions and ignores the fact that the hsps

are considered a "family" based on similar function, regardless of structure. First it is noted that the specification discloses the results of experiments employing gp96 exclusively. Given Applicant's present position, one of ordinary skill in the art would not expect that the generic hsps of Claim 1, nor the specific hsps, hsp70 and hsp90 of Claims 11 and 12, respectively, would function as claimed. Accordingly, Applicant appears to be arguing that while the art rejections should be withdrawn, a finding of lack of enablement (except for a method employing gp96) should be made. Additionally, Applicant has argued that restriction of the different hsps is improper and has cited MPEP 806.03,

"Single Embodiment, Claims Defining Same Essential Features Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition," (emphasis added by Examiner).

Applicant's attempt to argue that the MPEP was cited only to indicate a difference in breadth or scope would still allow for a finding of the obviousness of interchanging hsps. Finally, the Inventor himself has repeatedly taught that the hsps are closely related and interchangeable. See, for example the '119 patent "Stress proteins are among the most highly conserved proteins in existence," and "In addition, it has been discovered that the HSP60, Hsp70, and Hsp90 families are composed of proteins that are related to the stress proteins in sequence," (column 8). The Inventor goes on to teach that hsps can be considered stress proteins (column 8), and claims methods using them interchangeably. In the Inventor's 1995 publication (Suto et al., 1995, copy enclosed), the Inventor refers to the hsps collectively and teaches their use of common mechanisms of action.

Applicant argues that, "although the '119 patent may suggest that hsp70, hsp90, and gp96 function in a similar manner in the method disclosed therein, which is for treating cancer, the disclosure of the '119 patent does not support the general inference that hsps are interchangeable for all purposes."

It is the Examiner's position that the prior art, including the Inventor's own work, e.g., Suto et al., 1995, stresses the similarities of hsp function. Accordingly, there are two

possibilities, first, that hsps would be expected to have similar functions, and second that hsps would not. It is the Examiner's position that, based on the prior art as a whole, it is more likely that the hsps would be expected to have similar function than that they would not. It is the Examiner's position that it is not logical or consistent to, on the one hand, stress the similarities of a members of a protein family, but on the other, argue that the members would not be expected to act similarly in this particular situation, particularly in light of the Inventor's own teachings that hsps act through a common mechanism. Also again note Applicant's citing of MPEP 806.03 regarding the same essential characteristics of all hsps, which would seem to indicate that Applicant has found hsps similar enough to not be restrictable, even as species, but Applicant then argues that the use/substitution of different hsps is not obvious. It is the Examiner's position that Applicant's argument/position cannot be considered credible or consistent.

Applicant continues by arguing that in one instance in WO 95/15338, a bacterial stress protein (groES) was found to lack the biological activity of mammalian Early Pregnancy Factor. While this might be so, it is noted that the hsps of the instant claims are mammalian (Claim 8), even human (Claim 9), which would be much more likely to function by the similar mechanisms taught by the prior art.

Applicant concludes by arguing that the '803 patent discloses the immunosuppressive nature of Hsp60 only. It is the Examiner's position that if the '803 patent taught the use of additional hsps in the claimed method, no additional references would be needed in the rejection. The '119 patent (see particularly column 8) teaches the similarity of Hsp70 and Hsp90 to Hsp60, accordingly, the substitution of one for the other is obvious.

Finally note that Claim 32 has been added to the rejection. A method employing a combination of hsps, complexes, or peptides would be considered as obvious as a method employing individual hsps, complexes, or peptides. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

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7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
March 19, 2003